

# Certificate of Analysis

Product: <b>Extended IV Control</b>	Cat.No. <b>213286</b>	Lot No.: <b>QCX025006</b>	Expiration date: <b>2025-04-12</b>
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Origin: human erythrocytes from blood group A2B, A, B and O  
 Manufacturing Date: 25 FEB 2025  
 Preservative: Neomycin & Chloramphenicol  
 Storage: 2-8 °C  
 Manufacturing size: 4 x 6 ml

Criterion	Method	Specification	Results
<b>Tube QCX1, lot QCX125006</b>			
Specificity	Blood group testing by DG Gel	Blood group A2B CcD.Ee, K positive	Blood group A2B CcD.Ee, K positive
	Blood group testing by tube technique	Blood group A2B CcD.Ee, K positive	Blood group A2B CcD.Ee, K positive
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: negative O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: negative O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: negative O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: negative O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
Antibody screening	IAT Test by DG Gel with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
	IAT test by tube technique with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	14.7 %
Hemolysis at release	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.011 AU

<b>Tube QCX2, lot QCX225006</b>			
Specificity	Blood group testing by DG Gel	Blood group A CC <sup>w</sup> D.ee, Fy <sup>a</sup> negative	Blood group A CC <sup>w</sup> D.ee, Fy <sup>a</sup> negative
	Blood group testing by tube technique	Blood group A CC <sup>w</sup> D.ee, Fy <sup>a</sup> negative	Blood group A CC <sup>w</sup> D.ee, Fy <sup>a</sup> negative
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative	A <sub>1</sub> cells: negative A <sub>2</sub> cells: negative B cells: positive O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
Fy <sup>a</sup> Antibody screening	IAT test by DG Gel with Screen-Cyte	Screening cells Fy <sup>a</sup> positive: positive Screening cells Fy <sup>a</sup> negative: negative	Screening cells Fy <sup>a</sup> positive: positive Screening cells Fy <sup>a</sup> negative: negative
	IAT test by tube technique with Screen-Cyte cells	Screening cells Fy <sup>a</sup> positive: positive Screening cells Fy <sup>a</sup> negative: negative	Screening cells Fy <sup>a</sup> positive: positive Screening cells Fy <sup>a</sup> negative: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	14.8 %
Hemolysis after filling	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.012 AU
<b>Tube QCX3, lot QCX325006</b>			
Specificity	Blood group testing by DG Gel	Blood group B ccD.EE	Blood group B ccD.EE
	Blood group testing by tube technique	Blood group B ccD.EE	Blood group B ccD.EE
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: negative O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
Antibody screening	IAT Test by DG Gel with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
	IAT test by tube technique with Screen-Cyte cells	Screen-Cyte cells: negative	Screen-Cyte cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	14.8 %
Hemolysis after filling	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.008 AU

<b>Tube QCX4, lot QCX425006</b>			
Specificity	Blood group testing by DG Gel	Blood group O ccddee, K negative	Blood group O ccddee, K negative
	Blood group testing by tube technique	Blood group O ccddee, K negative	Blood group O ccddee, K negative
	Reverse-Typing by DG Gel	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: positive O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: positive O cells: negative
	Reverse-Typing by tube technique	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: positive O cells: negative	A <sub>1</sub> cells: positive A <sub>2</sub> cells: positive B cells: positive O cells: negative
	Direct Antiglobulin Test by DG Gel at release	negative	negative
	Direct Antiglobulin Test by tube technique at release	negative	negative
D Antibody screening	IAT test by DG Gel IgG	Ror cells: minimum weak positive R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive rr cells: negative	Ror cells: minimum weak positive R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive rr cells: negative
	IAT test by tube technique	Ror cells: minimum weak positive R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive rr cells: negative	Ror cells: minimum weak positive R <sub>1</sub> R <sub>1</sub> cells: minimum weak positive R <sub>2</sub> R <sub>2</sub> cells: minimum weak positive rr cells: negative
Concentration of suspension	Determination of Hematocrit	15.0 ± 2.0 %	15.0 %
Hemolysis after filling	Optical Density at 540nm	Absorbance ≤ 1.0 AU	Absorbance 0.007 AU

**The product passed the internal Quality Control procedure.**

**All human source material used in the manufacture of this product were tested and found negative for HBsAg and antibodies to HCV, HIV-1/ HIV-2.**

Date: 28 February 2025

Sascha Feuerhahn  
Technical Director

Medion Grifols Diagnostics AG in Düringen, Switzerland, is certified according to EN ISO 13485.